UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,346	06/23/2003	Catherine Burgess	15966-609 (CURA-109)	1810

7590 06/07/2006

JENELL LAWSON
INTELLECTUAL PROPERTY
555 LONG WHARF DRIVE
CURAGEN CORPORATION
NEW HAVEN, CT 06551

EXAMINER	
WEGERT, SANDRA L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,346	BURGESS ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 3/17/05.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 26 and 29, drawn to a *NOVX* polypeptide (SEQ ID NO: 2, 4, 6, 8 or 10), classified in class 530, subclass 350+.

II. Claims 5-14 and 30, drawn to a polynucleotide (SEQ ID NO: 1, 3, 5, 7 or 9) encoding a *NOVX* polypeptide, and vectors and host cells comprising the nucleic acid, classified in class 536, subclass 23.5+

III. Claims 15-17, 28 and 31, drawn to an antibody; classified in class 424, subclass 130.1+.

IV. Claim 18, drawn to a method for determining the presence or amount of a *NOVX* polypeptide in a sample; classified in class 435, subclass 7.1+.

V. Claim 19, drawn to a method for determining the presence or amount of a polynucleotide in a sample; classified in class 536, subclass 23.5+.

VI. Claim 20, drawn to a method for identifying an agent that binds to a *NOVX* polypeptide; classified in class 435, subclass 7.1+.

VII. Claim 21, drawn to a method for identifying an agent that modulates the expression of a *NOVX* polypeptide; classified in class 536, subclass 23.1+.

VIII. Claim 21, drawn to a method for identifying an agent that modulates the activity of a *NOVX* polypeptide; classified in class 435, subclass 7.1+.

IX. Claim 22, drawn to a method for modulating the activity of a *NOVX* polypeptide in a cell sample or in vitro; classified in class 435, subclass 7.1+.

X. Claims 23 and 34, drawn to a method of treating or preventing a NOVX protein-associated disorder by administering a polypeptide; classified in class 435, subclass 7.1+.

XI. Claims 24, 27 and 36, drawn to a method of treating or preventing a NOVX protein-associated disorder, by administering a polynucleotide; classified in class 536, subclass 23.5+.

XII. Claims 25 and 35, drawn to a method of treating or preventing a NOVX-associated disorder, by administering an antibody; classified in class 435, subclass 130.1+.

XIII. Claim 32, drawn to a method for determining the presence or predisposition to a disease by measuring expression of a *NOVX* polypeptide in a sample from a mammal; classified in class 536, subclass 23.5+.

IX. Claim 33, drawn to a method for determining the presence or predisposition to a disease by measuring the amount of a nucleic acid in a sample from a mammal; classified in class 536, subclass 23.5+.

Furthermore, applicant is required to elect *one sequence* from one of the following groups.

(a) SEQ ID NO: 2, 4, 6, 8 or 10.

(b) SEQ ID NO: 1, 3, 5, 7 or 9.

Sequences in Group (a) are drawn to polypeptides. Sequences in Group (b) are drawn to polynucleotides.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I-III are independent and distinct, each from the other, because their products possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The polypeptide of Group I can be used for treatment or can be used to make an antibody. The nucleic acids used in Group II can be used to make a hybridization probe or can be used in gene therapy as well as to make the protein of Group I.

Groups I and II are also related as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group III is neither used in nor produced by any the methods of

Group III. In addition, Inventions II and III comprise unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different structures, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different structures and effects.

Invention I is related to Inventions IV, VI, VIII and IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide can be used therapeutically or can be used to make the antibody of Group III.

Invention I is unrelated to Inventions V and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and different effects. The polypeptide is not used to bind nucleic acids for detection or to modify gene expression.

Invention II is unrelated to Inventions IV, VI, VIII and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and different effects. The nucleic acids are not used in binding assays involving the polypeptide.

Invention II is related to Inventions V and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the nucleic acid can be used therapeutically, or can be used to produce the polypeptide.

Invention III is related to Inventions IV and IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the antibody can be used to immunoprecipitate the polypeptide or can be used therapeutically.

Invention III is unrelated to Inventions V, VI, VII and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody is not used in nucleic acids hybridization methods or in assays to find agonists or antagonists of the polypeptide.

Inventions V-IX are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of Inventions V-IX are distinct, each from the other, related only in that they involve a NOVX gene or polypeptide. Hybridization binding assays, in vitro binding assays, treatments or detection assays all encompass different subjects

(cultured cells versus animals), different conditions, different protocols, different personnel, and all have differing chances of success.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because each protein or nucleic acid of Groups (a) and (b) requires a completely separate search, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Groups I through IX, and must additionally elect from Groups (a) or (b). Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection

or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**
Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER

SLW

1 June 2006